

Application No.: 09/882,630  
Amdt dated: January 11, 2006  
Reply to Office action of October 27, 2005

**Amendments to the Drawings:**

Figures 8 and 9 were amended to add callout "84" for the lumen of the elastomeric element "83." Support for this amendment is found in the Specification in the paragraph beginning on page 6, line 23 and in claims 28 and 31.

Attachment: Replacement Sheet

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**REMARKS/ARGUMENTS**

This Amendment is filed in response to the Office Action that was mailed on October 27, 2005. Claims 10, 12-14, 21-29 and 31 are pending in the application. Claims 24-27 have been previously withdrawn from consideration. By this Amendment, claims 13, 21, 28 and 29 are amended, claim 30 is canceled, and the Specification and drawings are amended. The amendments do not introduce new matter as they are fully supported by the claims and the specification, or are inherent characteristics of the specification. Applicants respectfully request reconsideration and allowance of all claims in view of the above amendments and the following remarks.

In the drawings, Figures 8 and 9 were amended to add callout (84) for the lumen of the elastomeric element (83). Support for this amendment is found in the Specification in the paragraph beginning on page 6, line 23 and in Claims 28 and 31.

Claim 13 was objected to because it appeared to be incomplete. By this Amendment, Claim 13 was amended to add the word "and" following the second element of the claim, to remove the word "and" following the third element of the claim, and to replace the semicolon at the end of the third element of the claim with a period. Applicants respectfully submit that this objection is now moot and respectfully request examination of Claim 13.

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Claims 10, 12 and 14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,290,666 to Devonec in view of U.S. Patent No. 3,332,424 to Minteer. The Examiner indicated that Devonec discloses all of the elements of independent claim 10 except for a concave surface. The Examiner further indicated that Minteer discloses a concave surface. Applicants respectfully traverse this rejection because Devonec does not disclose the claimed invention and Minteer does not correct this deficiency.

Claim 10 of the present Application includes a method for inserting a medical instrument into a urethra. The method includes "inserting the distal end of the tube into the urethra to an operating position in order to provide access for the medical instrument" and "moving the medical instrument distally into the proximal end of the lumen of the tube and through the lumen of the tube into the urethra...." As such, it is inherent that the tube is inserted into the urethra separate from the medical instrument and that the medical instrument is inserted into the urethra through the tube after the tube is placed in the operating position within the urethra. In Devonec, however, the tube (63) and the medical instrument (60) are inserted into the urethra together as an assembly for the purpose of inserting a prosthesis (8) across the striated muscular sphincter (5). (See Devonec, Figures 8-12 and column 6, lines 12 – 65.) Although it may be possible that the tube (63) of Devonec may be inserted into a urethra separate from the medical instrument (60), in no way does Devonec teach or suggest doing so. Additionally, Devonec teaches assembling the tube (63) and the medical instrument

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(60) together, along with the prosthesis (8), such that the tube abuts against the proximal end of the medical instrument formed by a "limit stop" (61). In this manner, it is not possible to move the medical instrument (60) of Devonec distally into the proximal end of the lumen of the tube (63) while the tube is positioned in the operating position within the urethra.

Claim 10 of the present Application also includes "during the moving step creating a distal force on the urethral access device" and "applying a proximal force on the distally-facing surface of the handle to oppose the distal force and maintain the access device in the operative position." For matters of clarification, as taught in Claim 10, the "urethral access device" includes the tube with a handle at the proximal end of the tube. Devonec fails to teach or suggest applying a proximal force on the distally facing surface of the handle to oppose the distal force of the access device. As stated above, Devonec teaches assembling the tube (63) and the medical instrument (60) together, along with the prosthesis (8), such that the tube abuts against the proximal end of the medical instrument formed by a "limit stop" (61). Devonec further teaches inserting the assembly into and through the urethra. In this manner, with the tube (63) of Devonec butted against the proximal end of the medical instrument (60), the proximal end of the medical instrument is intended to apply distal force against the tube to push the tube into the urethra. If a proximal force were applied to the distally facing surface of the handle of the tube to oppose the distal force of the medical instrument of Devonec, then it would not be possible to insert either the tube or the medical

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instrument into the urethra. Again, while the device of Devonec may be capable of being used in a manner similar to the method of Applicants' Claim 10, Devonec fails to teach or suggest the method of Applicants' Claim 10 and Minteer does nothing to correct the deficiency.

For the foregoing reasons, Applicants respectfully submit that neither Devonec nor Minteer, either together or alone, teaches each and every element of Applicants' independent Claim 10. As Applicants' independent Claim 10 is allowable over Devonec and Minteer, dependent Claims 12-14 and 23 are also allowable.

Claims 21-23, 28, 29 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,872,198 to Wilson et al. The Examiner indicated that Wilson et al. disclose all of the elements of independent claims 21 and 28 except for removing a portion of the elongate tube to shorten the length of the tube generally to the desired length. The Examiner further indicated that it would have been a matter of design choice to vary the length of the tube, since such a modification would have involved a mere change in the size of a component. Applicants respectfully traverse this rejection because Wilson et al. do not disclose the invention claimed in Claims 21 and 28. For clarification purposes, Applicants point out that Wilson et al. use the term "proximal" to refer to the portion of a catheter that is nearest the end of the catheter that is inserted into a patient and use the term "distal" to refer to the portion of the catheter that is furthest from the insertion end. (See Wilson et al., column 6, lines 28-37.) In the

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present application, Applicants use the term "proximal" to refer to the portion of the device closest to the user, or furthest from the end that is inserted into a patient, and use the term "distal" to refer to the portion of the device that is furthest from the user, or nearest the end that is inserted into the patient. Throughout these remarks, Applicants will continue to use the term "proximal" to refer to the portion of the device that is closest to the user and use the term "distal" to refer to the portion of the device that is furthest from the user.

Applicants appreciate the Examiner's acknowledgement that Wilson et al. do not teach removing a portion of the elongate tube to shorten the length of the tube generally to the desired length. However, Applicants respectfully submit that removing a portion of the elongate tube as claimed is not merely a design choice to vary the length of the tube as suggested by the Examiner. As claimed, the portion of the elongate tube is removed to shorten the length of the tube while the handle is engaged with the tube. More particularly, with the engagement apparatus in the first state, a portion of the elongate tube that is proximal to the handle is removed to shorten the length of the tube to the desired length. The handle is then moved to a predetermined proximal location on the tube and the engagement apparatus is placed in the second state to fix the handle to the tube.

Based on the design of Wilson et al., the elongate tube (18) of Wilson et al. cannot extend proximally of "handle" (72) while the handle is engaged with the tube.

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More particularly, Figure 2 of Wilson et al. depicts a compression-fitting (58) portion of the "handle" having a cannula (66) extending distally therefrom. The cannula (66) extends into the lumen of tube (18) while the proximal end of the tube (18) abuts against the distal end of the compression fitting (58), thereby preventing the tube (18) from extending proximally beyond the distal end of the compression fitting (58). For this reason, in Wilson et al. there is no portion of the elongate tube (18) proximal to the compression fitting (72) to remove while the compression fitting is engaged with the tube (18), and nothing in Wilson et al. teaches or suggests doing so.

By this amendment, Applicants amended independent Claim 21 to clarify that it is a portion of the tube proximal to the handle that is removed while the handle is engaged with the tube and that the handle is moved to a predetermined proximal location along the tube. Support for the amendment is found in the drawings, on page 7 of the specification in the paragraph beginning at line 8 and the paragraph beginning at line 14, and in the claims as originally filed.

For the foregoing reasons, Applicants respectfully submit that Wilson et al. fails to teach or suggest each and every element of independent Claim 21 of the present Application. As Applicants' independent Claim 21 is allowable over Wilson et al., dependent Claim 22 is also allowable.

Applicants respectfully express their appreciation to the Examiner for indicating that Claim 30 was objected to as being dependent upon a rejected base claim, but

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would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants amended independent Claim 28 to include all of the elements of dependent claim 30 and canceled Claim 30. For this reason, Applicants respectfully submit that amended Claim 28 is in condition for allowance. As dependent Claims 29 and 31 depend from Claim 28, Applicants respectfully submit that they are also in condition for allowance.

Dependent Claim 23 derives from independent Claim 10, not from Claim 21. As stated above, Applicants respectfully submit that Claim 23 is allowable as dependent from allowable Claim 10.

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner believes that a telephone conference with Applicants' attorney might expedite prosecution of the application, the Examiner is invited to call at the telephone number indicated below.

Sincerely

APPLIED MEDICAL RESOURCES

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Attachments